

**II. REMARKS**

Independent claims 21 and 31 have been amended to recite

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer’s tongue,”

as supported on page 2, line 23, to page 3, line 2, and page 7, lines 10-15, and on page 9, lines 3-8, of Applicant’s specification as originally filed.

Independent claims 36 has been amended to recite

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva,”

as supported on page 2, line 23, to page 3, line 2, and page 7, lines 10-15, and on page 9, lines 3-8, of Applicant’s specification as originally filed.

Independent claims 37 has been amended to recite

“dispensing the medication into the wearer’s mouth, wherein the medication is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the medication over time in the wearer’s saliva,”

as supported on page 2, line 23, to page 3, line 2, and page 7, lines 10-15, and on page 9, lines 3-8, of Applicant’s specification as originally filed.

Independent claims 38 and 39 have been amended to recite

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue by diffusing the substance from the stud into the wearer’s mouth over time in the wearer’s saliva,”

as supported on page 2, line 23, to page 3, line 2, and page 7, lines 10-15, and on page 9, lines 3-8, of Applicant’s specification as originally filed.

Independent claims 44 and 45 have been amended to recite

“dispensing the substance into the wearer’s mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer’s tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer’s tongue over time in the wearer’s saliva,”

as supported on page 2, line 23, to page 3, line 2, and page 7, lines 10-15, and on page 9, lines 3-8, of Applicant's specification as originally filed.

The present amendment adds no new matter to the above-captioned application.

**A. The Invention**

The present invention pertains broadly to a method for dispensing a substance into a mouth, such as could be used to dispense a breath freshener, a flavoring agent, a medication, or a combination of these substances. In one embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 21. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 31. In yet another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 36. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 37. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 38. In yet another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 39. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 44. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 45.

Various other embodiments, in accordance with the present invention, are recited in the dependent claims. All of the embodiments, in accordance with the present invention, provide the advantage of using a “mouth and tongue stud” to dispense a substance into a wearer’s mouth. As would be understood by a person of ordinary skill in the art, a “mouth and tongue stud” is a particular kind of jewelry having features allowing it to be disposed in the mouth of a wearer.

**B. The Rejection**

Claims 21-27, 31, 36, 37, 44 and 46 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kapling, Jr. (U.S. Patent 6,026,659, hereafter the “Kapling Patent”) and Kasdin et al. (U.S. Patent 3,503,127, hereafter the “Kasdin Patent”). Claims 38 and 48 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Kapling Patent in view of Sipos (U.S. Patent 3,600,807, hereafter the “Sipos Patent”). Claim 31, 27, 39, 42, 43 and 45 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Kapling Patent in view of Cox (U.S. Patent 4,959,052, hereafter the “Cox Patent”). Claim 49 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Kapling Patent in view of the Cox Patent, and further in view of the Kasdin Patent.

I respectfully traverse the rejections and request reconsideration of the application for the following reasons.

**C. Applicant’s Arguments**

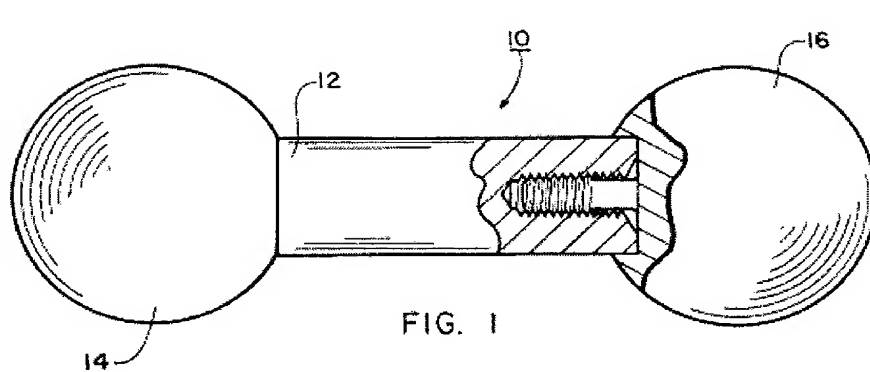
A prima facie case of obviousness requires a showing that the scope and content of the prior art teaches each and every element of the claimed invention, and that the prior art provides some teaching, suggestion or motivation, or other reason, to combine the references to produce the claimed invention. KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1742 (2007); In re Oetiker, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). A proper rejection under Section 103 also requires showing (1) that the prior art would have suggested to a person of ordinary skill in the art that they should make

the claimed device or carry out the claimed process, (2) that the prior art would have revealed to a person of ordinary skill in the art that in so making or doing, there would have been a reasonable expectation of success, and (3) both the suggestion and the reasonable expectation of success must be found in the prior art and not in the applicants' disclosure. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). An obviousness analysis, however, is not a rigid formulaic analysis, but is a flexible determination grounded in the facts of the case. KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1739 (2007). Indeed, the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007).

In the present case, the Examiner has failed to establish a prima facie case of obviousness against the claims as amended because the combination of the Kapling Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent, (i) fails to teach each and every limitation of the claims as amended, (ii) the Examiner has failed to establish any legitimate reason to justify the combination, and (iii) the Examiner has failed to establish that the combination would be enabling and/or that by making the combination a person of ordinary skill in the art would have a reasonable expectation of arriving at the claimed invention.

**i. The Kapling Patent**

U.S. Patent 6,026,659, the Kapling Patent, discloses a "body jewelry device and method of making the same," wherein, as shown in Figure 1, the body jewelry device (10) includes a post (12) with cap (14) coupled to one end of the post (12) and cap (16) coupled to the other end of the post (12), (See Kapling Patent, col. 3, lines 38-42). Figure 1 of the Kapling Patent is reproduced below. The Kapling Patent, at col. 3, lines 43-44, discloses that the post (12) is disposed in the pieced passageway in a wearer's tongue.



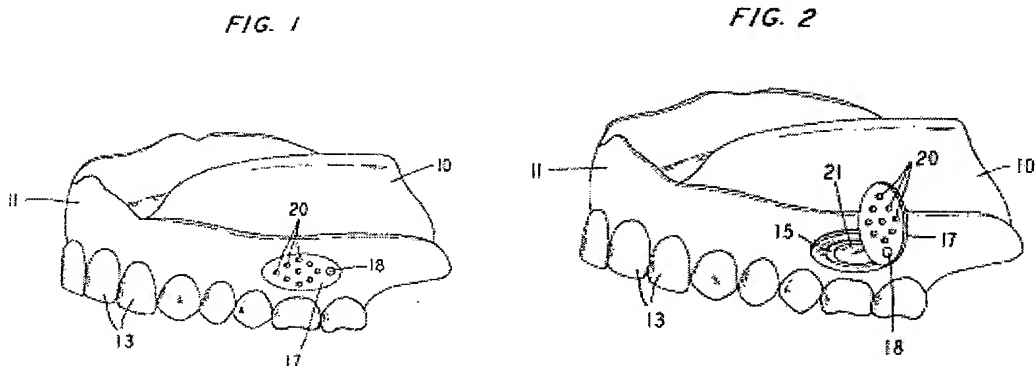
As admitted by the Examiner (Office Action, dated March 10, 2010, at 3, lines 7-12, and at 5, lines 14-19, and at 7, lines 14-19; Office Action, dated November 11, 2006, at 3, lines 18-21; Office Action, dated March 24, 2008, at 18-24; Office Action, dated November 26, 2008, at 3, lines 18-24), the Kapling Patent does not teach, or suggest, (i) “providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud” as recited by independent claims 21, 31, 36, 37, 38, 39, 44 and 45, (ii) “dispensing the substance into the wearer’s mouth, wherein the substance is dispensed...solely by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21 and 31, (iii) “dispensing the substance into the wearer’s mouth” as recited by independent claims 36, 38 and 39, (iv) “dispensing the medication into the wearer’s mouth” as recited by independent claim 37, (v)

“dispensing the substance into the wearer’s mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form,”

as recited by independent claims 44 and 45.

## **ii. The Kasdin Patent**

The Kasdin Patent discloses a “denture with a receptable therein” as shown in Figures 1 and 2 that are reproduced below. As shown in Figures 1 and 2 of the Kasdin Patent, and upper denture includes a palate section (10), a flange portion (11) and false teeth (13), wherein a cup (15) is built into the flange portion (11), (Kasdin Patent, col. 1, line 57, to col. 2, line 11). A pill (21) may be placed in the cup (15), and secured in place by a cap (17) provide with apertures (20) and a hinge



Figures 1 and 2 of the Kasdin Patent

post (18) so that saliva may reach the pill and be sweetened by the essence of the pill (Kasdin Patent, col. 2, lines 11-59)

However, the Kasdin Patent does not teach, or even suggest, (i) “providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud” as recited by independent claims 21, 31, 36, 37, 38, 39, 44 and 45. Furthermore, the Kasdin Patent does not teach, or even suggest, (ii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer’s tongue,”

as recited by claims 21 and 31, (iii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva,”

as recited by claim 36, (iv)

“dispensing the medication into the wearer’s mouth, wherein the medication is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the medication over time in the wearer’s saliva,”

as recited by claim 37, (v)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue by diffusing the substance from the stud into the wearer’s mouth over time in the wearer’s saliva,”

as recited by claims 38 and 39, and (vi)

“dispensing the substance into the wearer’s mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer’s tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer’s tongue over time in the wearer’s saliva,”

as recited by claims 44 and 45.

As shown in Figures 1 and 2 of the Kasdin Patent, the location of the cup (15) on the exterior, buccal surface of the dentures is such that the chemicals flowing from the pill (21) in cup (15) would be dispensed to the labial or buccal mucosa of the mouth, and would not be “dispensed on or below, or on and below, the wearer’s tongue” as recited by independent claims 21, 31, 36, 37, 44 and 45 as amended, and it would not be “dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue” as recited by independent claims 38 and 39. In fact, the Kasdin Patent teaches away from dispensing the sweet chemical on or below, or on and below, the tongue because the Kasdin Patent discloses dispensing the sweet chemical at a location remote to the tongue and in a direction away from the tongue as would be inherent to the location of the cup (15) on the exterior buccal surface of the denture.

**a. The Kasdin Patent is Non-analogous Art**

The subject matter disclosed by the Kasdin Patent pertains to “dentures,” which is non-analogous art. A reference is analogous art if it is from the same field of endeavor (i.e., the invention and the prior art device are similar in structure and function), and if a reference is outside the inventor’s field of endeavor, the reference may be analogous art only if the reference is reasonably pertinent to the particular problem with which the inventor is involved. State Contracting & Engineering Corp. v. Condotte America, Inc., 346 F.3d 1057, 1069 (Fed. Cir. 2003). In this case, the Kasdin Patent pertains to “dentures,” which have a substantially different structure and function than the subject matter of the present invention, which pertains to the field of “mouth and tongue studs” (i.e., oral body piercings). Therefore, the Examiner should concede that the “dentures” and method

for dispensing sweet chemicals from the dentures onto the labial or buccal mucosa of the mouth  
pertain to a substantially different field of endeavor than that of the present invention, which pertains  
to a “mouth and tongue stud” and a method for dispensing a substance on or above, or on and above,  
the tongue of the mouth.

In addition, the subject matter of the Kasdin Patent is not reasonably pertinent to the particular problem with which the present inventor has addressed. In particular, the present invention involves providing a mouth and tongue stud including a means for dispensing a substance, wherein the means for dispensing a substance is used to dispense the substance to the tongue and sublingual regions of the mouth (See, e.g., Applicants’ specification, at 2, lines 16, to 3, line 2). The device and methods disclosed by the Kasdin Patent involve the use of a modified denture, and not to the use of a mouth and tongue stud, and the problem the Kasdin Patent addresses does not include how to dispense a substance to the tongue or sublingual regions of the mouth. Therefore, the Examiner should conclude that the Kasdin Patent is not reasonably pertinent to the particular problem the inventor of the subject matter of the above-captioned application faced and addressed.

Because the subject matter disclosed by the Kasdin Patent pertains to a substantially different field of endeavor than that of the presently claimed invention, and because the subject matter disclosed by the Kasdin Patent is not reasonably pertinent to the particular problem with which the present invention is involved, Applicant has shown that the Kasdin Patent is non-analogous art with respect to the subject matter of the claimed invention.

### **iii. The Cox Patent**

The Cox Patent discloses an “applicator for dispensing active substances,” as shown in Figures 1, 2, 11, 12 and 13, for example. According to the Cox Patent, the oral applicator for the application of an active substance is in the form of a hollow structure corresponding substantially in shape and dimensions to an external form of a crown (2) of one or more natural teeth and adapted to contain the active substance, wherein the hollow structure (4) has one or more passage openings (5)



for the controlled release of certain amounts of the active substance, wherein the passage openings (5) are formed in a buccal and/or palatal or lingual portion of the crown (5) for the passage of saliva and of the active substance dissolved therein (See Abstract of the Cox Patent, and col. 5, lines 15-68).

However, the Cox Patent does not teach, or even suggest, (i) “providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud” as recited by independent claims 21, 31, 36, 37, 38, 39, 44 and 45. Furthermore, the Cox Patent does not teach, or even suggest, (ii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer’s tongue,”

as recited by claims 21 and 31, (iii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva,”

as recited by claim 36, (iv)

“dispensing the medication into the wearer’s mouth, wherein the medication is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the medication over time in the wearer’s saliva,”

as recited by claim 37, (v)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue by diffusing the substance from the stud into the wearer’s mouth over time in the wearer’s saliva,”

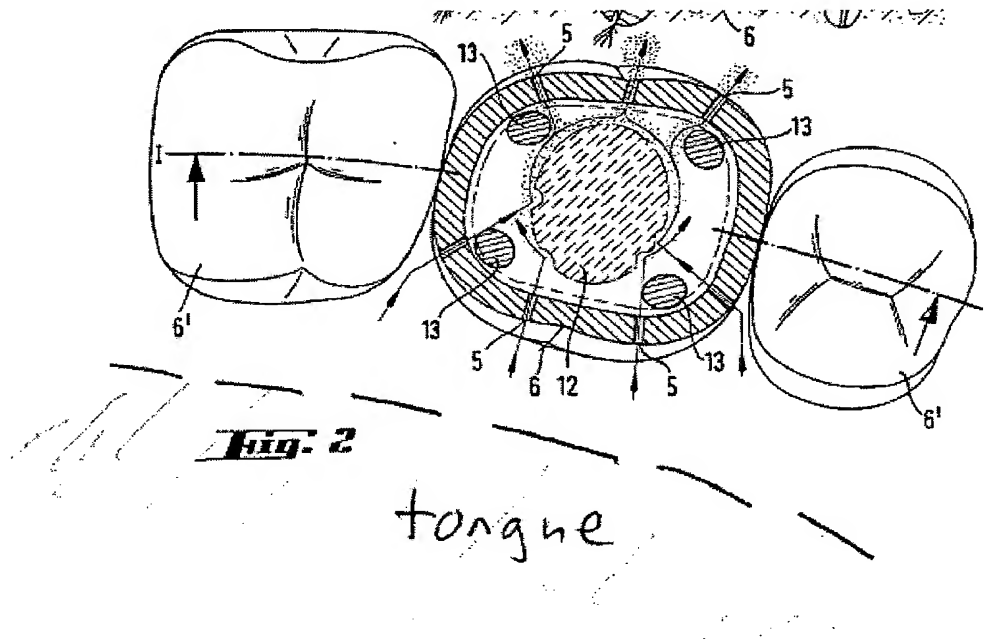
as recited by claims 38 and 39, and (vi)

“dispensing the substance into the wearer’s mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer’s tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer’s tongue over time in the wearer’s saliva,”

as recited by claims 44 and 45.

As shown in Figures 2, 11 and 13 of the Cox Patent, the flow of saliva through openings (5)

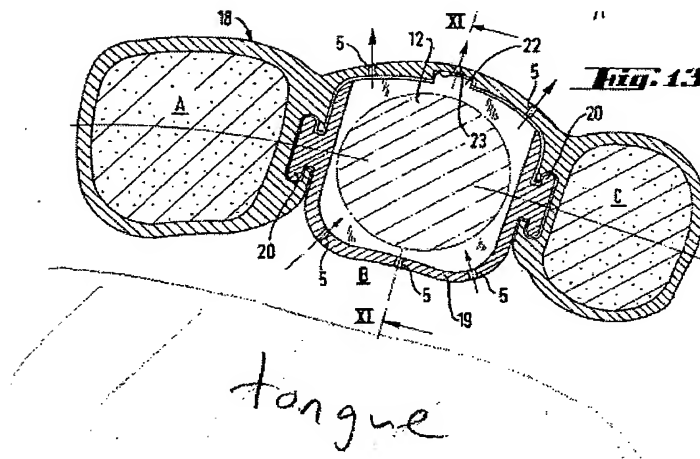
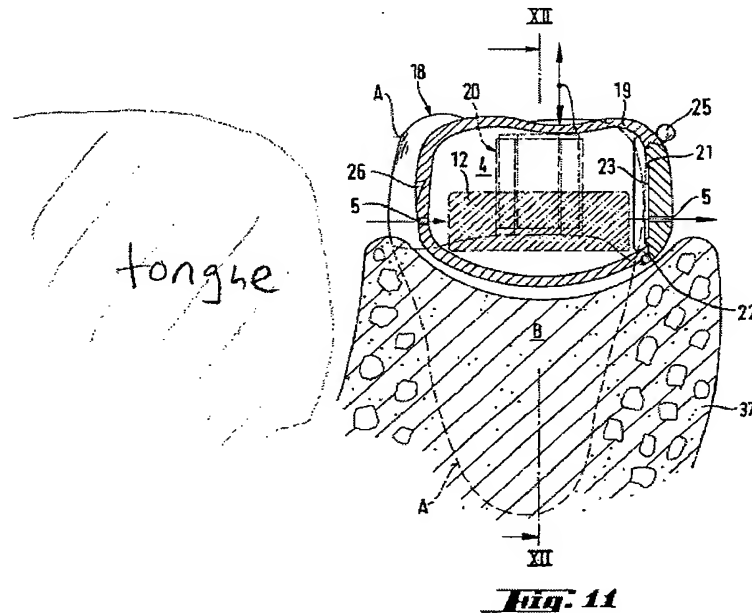
on the lingual side of the crown (2) and out the openings (5) on the buccal side of the crown (2) is such that the substance is dispensed on the buccal side of the crown (2) and not on the lingual side of the crown (2), (Cox Patent, col. 6, lines 7-13). This fact is evident from the size and curvature of the teeth, and progression of teeth from molars to premolars (See, e.g., GRAY'S ANATOMY 1413-1417 and 1432 (Carmine D. Clemente ed., Lea & Fabringer 1985), a copy of which is filed herewith as "Exhibit AD"), from which a person of ordinary skill in the art can deduce where the location of the tongue would be in the figures of the Cox Patent. To aid visualization of where the tongue is located relative to the other structures in Figures 2, 11 and 13, Applicant provides below annotated versions of Figures 2, 11 and 13 of the Cox Patent.



Annotated Figure 2 of Cox Patent

As evident from annotated Figures 2, 11 and 13 of the Cox Patent, the flow of saliva as shown by the arrows passing through openings (5) is away from the tongue. Consequently, any substance dispensed from the hollow chamber (4) of the crown (2) is dispensed on the buccal side of the teeth and is directed away from the tongue. In other words, the substance flowing from the hollow chamber (4) through openings (5) of the crown (2) would be dispensed to the buccal mucosa of the mouth, and would not be "dispensed on or below, or on and below, the wearer's tongue" as

recited by independent claims 21, 31, 36, 37, 44 and 45 as amended, and it would not be “dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue” as recited by independent claims 38 and 39. In fact, the Cox Patent teaches away from dispensing the substance on or below, or on and below, the tongue because the Cox Patent discloses dispensing the substance at a location remote to the tongue and in a direction away from the tongue as is evident from the direction of saliva flow illustrated through openings (5) of the crown (2) in Figures 2, 11 and 13 of the Cox Patent.



Annotated Figures 11 and 13 of the Cox Patent

**a. The Cox Patent is Non-analogous Art**

The subject matter disclosed by the Cox Patent pertains to a modified crown for a tooth, which pertains to non-analogous art. A reference is analogous art if it is from the same field of endeavor (i.e., the invention and the prior art device are similar in structure and function), and if a reference is outside the inventor's field of endeavor, the reference may be analogous art only if the reference is reasonably pertinent to the particular problem with which the inventor is involved. State Contracting & Engineering Corp. v. Condotte America, Inc., 346 F.3d 1057, 1069 (Fed. Cir. 2003). In this case, the Cox Patent pertains to an artificial crown for a tooth, which has a substantially different structure and function than the subject matter of the present invention, which pertains to the field of "mouth and tongue studs" (i.e., oral body piercings). Therefore, the Examiner should concede that the dental "crown" and method for dispensing substances from the dental crown onto the buccal mucosa of the mouth pertain to a substantially different field of endeavor than that of the present invention, which pertains to a "mouth and tongue stud" and a method for dispensing a substance on or above, or on and above, the tongue of the mouth.

In addition, the subject matter of the Cox Patent is not reasonably pertinent to the particular problem with which the present inventor has addressed. In particular, the present invention involves providing a mouth and tongue stud including a means for dispensing a substance, wherein the means for dispensing a substance is used to dispense the substance to the tongue and sublingual regions of the mouth (See, e.g., Applicants' specification, at 2, lines 16, to 3, line 2). The device and methods disclosed by the Cox Patent involve the use of a modified dental crown, and not to the use of a mouth and tongue stud, and the problem the Cox Patent addresses does not include how to dispense a substance to the tongue or sublingual regions of the mouth. Therefore, the Examiner should conclude that the Cox Patent is not reasonably pertinent to the particular problem the inventor of the subject matter of the above-captioned application faced and addressed.

Because the subject matter disclosed by the Cox Patent pertains to a substantially different

field of endeavor than that of the presently claimed invention, and because the subject matter disclosed by the Cox Patent is not reasonably pertinent to the particular problem with which the present invention is involved, Applicant has shown that the Cox Patent is non-analogous art with respect to the subject matter of the claimed invention.

**iv. The Sipos Patent**

The Sipos Patent discloses an “odiferous dental apparatus” as shown in Figure 2 and 3, which are reproduced below for convenience. According to the Sipos Patent, an oral apparatus for making the mouth pleasantly tasteful and exhaled air aromatically pleasant is provided in an artificial tooth (14) or other dental appliance (i.e., dentures) and includes an opening (20) therein filled with either absorbent fibrous material (18) saturated with an air-refreshant fluid or a removable insert (16) for containing such fluid (See Abstract of the Sipos Patent, col. 2, lines 13-74).

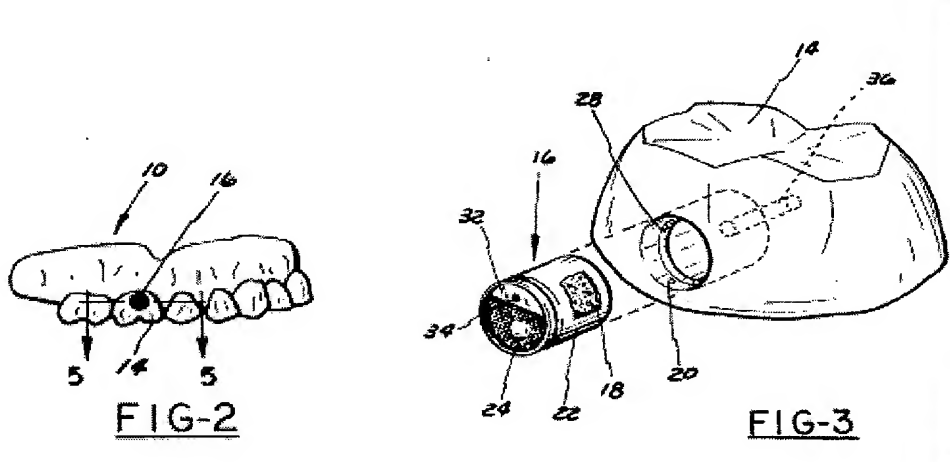


Figure 1 of the Sipos Patent

However, the Sipos Patent does not teach, or even suggest, (i) “providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud” as recited by independent claims 21, 31, 36, 37, 38, 39, 44 and 45. Furthermore, the Sipos Patent does not teach, or even suggest, (ii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue

solely by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer's tongue,"

as recited by claims 21 and 31, (iii)

"dispensing the substance into the wearer's mouth, wherein the substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva,"

as recited by claim 36, (iv)

"dispensing the medication into the wearer's mouth, wherein the medication is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the medication over time in the wearer's saliva,"

as recited by claim 37, (v)

"dispensing the substance into the wearer's mouth, wherein the substance is dispensed into the wearer's mouth on or below, or on and below, the wearer's tongue by diffusing the substance from the stud into the wearer's mouth over time in the wearer's saliva,"

as recited by claims 38 and 39, and (vi)

"dispensing the substance into the wearer's mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer's tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer's tongue over time in the wearer's saliva,"

as recited by claims 44 and 45.

As shown in Figures 2 and 3 of the Sipos Patent, the location of the opening (20) on the exterior, buccal surface of the dentures is such that the fluids flowing from the insert (16) in opening (20) would be dispensed to the labial or buccal mucosa of the mouth, and would not be "dispensed on or below, or on and below, the wearer's tongue" as recited by independent claims 21, 31, 36, 37, 44 and 45 as amended, and it would not be "dispensed into the wearer's mouth on or below, or on and below, the wearer's tongue" as recited by independent claims 38 and 39. In fact, the Sipos Patent teaches away from dispensing the fluids on or below, or on and below, the tongue because the Sipos Patent discloses dispensing the fluids at a location remote to the tongue and in a direction away from the tongue as would be inherent to the location of the insert (16) on the exterior buccal surface of the denture.

**a. The Sipos Patent is Non-analogous Art**

The subject matter disclosed by the Sipos Patent pertains to “dentures” (Sipos Patent, col. 2, lines 12-14), which pertains to non-analogous art. A reference is analogous art if it is from the same field of endeavor (i.e., the invention and the prior art device are similar in structure and function), and if a reference is outside the inventor’s field of endeavor, the reference may be analogous art only if the reference is reasonably pertinent to the particular problem with which the inventor is involved. State Contracting & Engineering Corp. v. Condotte America, Inc., 346 F.3d 1057, 1069 (Fed. Cir. 2003). In this case, the Sipos Patent pertains to “dentures,” which have a substantially different structure and function than the subject matter of the present invention, which pertains to the field of “mouth and tongue studs” (i.e., oral body piercings). Therefore, the Examiner should concede that the “dentures” and method for dispensing fluids from the dentures onto the buccal mucosa of the mouth pertain to a substantially different field of endeavor than that of the present invention, which pertains to a “mouth and tongue stud” and a method for dispensing a substance on or above, or on and above, the tongue of the mouth.

In addition, the subject matter of the Sipos Patent is not reasonably pertinent to the particular problem with which the present inventor has addressed. In particular, the present invention involves providing a mouth and tongue stud including a means for dispensing a substance, wherein the means for dispensing a substance is used to dispense the substance to the tongue and sublingual regions of the mouth (See, e.g., Applicants’ specification, at 2, lines 16, to 3, line 2). The device and methods disclosed by the Sipos Patent involve the use of a modified denture, and not to the use of a mouth and tongue stud, and the problem the Sipos Patent addresses does not include how to dispense a substance to the tongue or sublingual regions of the mouth. Therefore, the Examiner should conclude that the Sipos Patent is not reasonably pertinent to the particular problem the inventor of the subject matter of the above-captioned application faced and addressed.

Because the subject matter disclosed by the Sipos Patent pertains to a substantially different

field of endeavor than that of the presently claimed invention, and because the subject matter disclosed by the Sipos Patent is not reasonably pertinent to the particular problem with which the present invention is involved, Applicant has shown that the Sipos Patent is non-analogous art with respect to the subject matter of the claimed invention.

**v. Summary of the Disclosures**

The Kapling Patent discloses a conventional bar bell stud that is inserted through a passageway in a user's tongue. The Kapling Patent does not teach, or suggest, any "means for dispensing a substance" and/or any related features thereof.

The Kasdin Patent and the Sipos Patent each disclose dentures modified to dispense a chemical or liquid to the labial or buccal mucosa of the mouth, and away from the tongue. Neither the Kasdin Patent nor the Sipos Patent teach, or suggest, a "mouth and tongue stud including a means for dispensing a substance" as claimed. In fact, the Kasdin Patent and the Sipos Patent are non-analogous art with respect the subject matter of the presently claimed invention.

The Cox Patent discloses a crown for a tooth, wherein the crown is modified to dispense a substance towards the buccal mucosa of the mouth, and away from the tongue. Neither the Kasdin Patent nor the Sipos Patent teach, or suggest, a "mouth and tongue stud including a means for dispensing a substance" as claimed. In fact, the Kasdin Patent and the Sipos Patent are non-analogous art with respect the subject matter of the presently claimed invention.

The combination of the disclosures of the Kapling Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent does not teach, or even suggest, (i) "**providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud**" as recited by independent claims 21, 31, 36, 37, 38, 39, 44 and 45, (ii)

**"dispensing the substance into the wearer's mouth, wherein the substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva so that the**



dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer's tongue,"

as recited by claims 21 and 31, (iii)

"dispensing the substance into the wearer's mouth, wherein the substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva,"

as recited by claim 36, (iv)

"dispensing the medication into the wearer's mouth, wherein the medication is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the medication over time in the wearer's saliva,"

as recited by claim 37, (v)

"dispensing the substance into the wearer's mouth, wherein the substance is dispensed into the wearer's mouth on or below, or on and below, the wearer's tongue by diffusing the substance from the stud into the wearer's mouth over time in the wearer's saliva,"

as recited by claims 38 and 39, and (vi)

"dispensing the substance into the wearer's mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer's tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer's tongue over time in the wearer's saliva,"

as recited by claims 44 and 45.

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against any of the amended claims of the above-captioned application.

**vi. No Legitimate Reason to Combine the Disclosures of the Kasdin Patent, the Cox Patent and the Sipos Patent with the Kapling Patent**

A proper rejection under Section 103 requires showing (1) that a person of ordinary skill in the art would have had a legitimate reason to attempt to make the composition or device, or to carry out the claimed process, and (2) that the person of ordinary skill in the art would have had a reasonable expectation of success in doing so. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). In this case, the Examiner has failed to establish a proper teaching,

motivation, suggestion, or any legitimate reason whatsoever, to justify combining the Kapling Patent's disclosed device with the disclosures of the Kasdin Patent, the Cox Patent, and/or the Sipos Patent for the following reasons.

First, while the Kapling Patent discloses a conventional bar bell stud for inserting into a tongue piercing, the conventional bar bell stud does not include any means for dispensing a substance. On the other hand, the Kasdin Patent, the Cox Patent and the Sipos Patent each pertain to non-analogous art as established above. It is a well-settled proposition that a prima facie case of obviousness cannot be based on non-analogous art. In re Clay, 23 U.S.P.Q.2d 1058, 1061 (Fed. Cir. 1992). Therefore, a person of ordinary skill in the art would have no legitimate reason whatsoever to make the combinations asserted by the Examiner.

Second, each of the Kasdin Patent, the Cox Patent, and the Sipos Patent disclose methods for dispensing substances to the labial or buccal mucosa of the mouth and away from the tongue. Therefore, each of the Kasdin Patent, the Cox Patent and the Sipos Patent actually teaches away from the presently claimed invention. It is a well-settled proposition that a prima facie case of obviousness cannot be based on prior art disclosures that actually teach away from the claimed invention. McGinley v. Franklin Sports Inc., 60 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 2001).

In sum, because the Kasdin Patent, the Cox Patent and the Sipos Patent are each non-analogous art with respect to the presently claimed invention, and/or because the Kasdin Patent, the Cox Patent, and the Sipos Patent teach away from the claimed invention, the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 31, 36-39 and 42-49, as amended, of the above-captioned application.

**vii. No Reasonable Expectation of Success Even if the Combinations Proposed  
by the Examiner Were Made**

A proper rejection under Section 103 requires showing (1) that a person of ordinary skill in the art would have had a legitimate reason to attempt to make the composition or device, or to carry out the

claimed process, and (2) that the person of ordinary skill in the art would have had a reasonable expectation of success in doing so. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). In this case, assuming that the Examiner has established a legitimate reason to justify the combination of the Kapling Patent with the Kasdin Patent and/or the Cox Patent and/or the Sipos Patent (which is a completely invalid assumption), the Examiner has still failed to establish that a person of ordinary skill in the art would have had a reasonable expectation of success of arriving at the claimed invention if the combinations asserted by the Examiner were made.

Specifically, the Cox Patent discloses modifying an artificial tooth so that it may dispense a substance. The Kasdin Patent and the Sipos Patent each disclose modifying an external buccal portion of a denture so that it may dispense a substance. The device disclosed by the Kapling Patent has no structure even remotely similar the structure of Kasdin's or Sipos's dentures, or to Cox's crown. Therefore, a person of ordinary skill in the art would have lacked sufficient guidance to successfully modify Kaplan's bar bell structure to arrive at the presently claimed invention. Moreover, each one of the Kasdin Patent, the Cox Patent and the Sipos Patent discloses dispensing the substance to the labial or buccal mucosa of the mouth, and away from the tongue. Therefore, a person of ordinary skill in the art would not have a reasonable expectation of success of modifying the device disclosed by the Kapling Patent so that it would dispense a substance "on or below, or on and below, the wearer's tongue" in accordance with claims 21, 31, 36, 37, 38, 39, 44 and 45 as amended.

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 31, 36-39 and 42-49 of the above-captioned application.

### **III. CONCLUSION**

For all of the above reason, the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 31, 36-39 and 42-49 because the combination of the Kapling Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent, (i) fails to teach each and every

limitation of the claims, and (ii) the Examiner has failed to establish any legitimate reason whatsoever to justify the alleged combinations, and (iii) the Examiner has failed to establish that a person of ordinary skill in the art would have had a reasonable expectation of success of obtaining the claimed invention even if the combinations of the Kapling Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent, as asserted by the Examiner, were made.

For all of the above reasons, claims 21-27, 31, 36-39 and 42-49 are in condition for allowance and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below-signed Applicant.

Respectfully submitted,

GRIFFIN & SZIPL, PC

A handwritten signature in black ink, appearing to read 'W. Scott Ashton', is written over a horizontal line.

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